

105TH CONGRESS
1ST SESSION

H. R. 2972

To direct the Secretary of Health and Human Services to establish a continuous quality improvement program for providers that furnish services under the Medicare Program to individuals with end stage renal disease, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 8, 1997

Mr. STARK introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To direct the Secretary of Health and Human Services to establish a continuous quality improvement program for providers that furnish services under the Medicare Program to individuals with end stage renal disease, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “ESRD Continuous
5 Quality Improvement Program Act of 1997”.

1 **SEC. 2. ESTABLISHMENT OF CONTINUOUS QUALITY IM-**
2 **PROVEMENT PROGRAM FOR ESRD FACILI-**
3 **TIES UNDER MEDICARE.**

4 Section 1881 of the Social Security Act (42 U.S.C.
5 1395rr) is amended by adding at the end the following
6 new subsection:

7 “(h)(1)(A) Not later than 1 year after the date of
8 the enactment of this subsection, the Secretary shall es-
9 tablish a quality improvement program (hereafter in this
10 subsection referred to as the ‘CQI Program’) for providers
11 of services and renal dialysis facilities under this section.
12 In establishing the CQI Program, the Secretary shall con-
13 sult with representatives of providers of services and renal
14 dialysis facilities (including facility administrators,
15 nephrologists, dietitians, social workers, and nurses), pa-
16 tients of such providers and facilities, and quality improve-
17 ment experts.

18 “(B) Under the CQI Program—

19 “(i) the network administrative organizations
20 (as defined in paragraph (7)) shall provide informa-
21 tion, training, and technical assistance described in
22 paragraph (2);

23 “(ii) the Secretary shall establish and publish in
24 ESRD Core Indicators as described in paragraph
25 (3);

1 “(iii) the Secretary shall collect and analyze
2 data from providers and facilities as described in
3 paragraph (4);

4 “(iv) the Secretary shall identify and reward
5 outstanding providers and facilities as described in
6 paragraph (5); and

7 “(v) the Secretary shall identify and provide for
8 additional training to providers and facilities in need
9 of such training as described in paragraph (6).

10 “(2) Network administrative organizations shall per-
11 form the following functions:

12 “(A) Provide for the routine and timely meas-
13 urement and statistical evaluation, and feedback to
14 providers of services and renal dialysis facilities, of
15 the processes and outcomes of care for kidney trans-
16 plant, hemodialysis, and peritoneal dialysis patients,
17 using, among other data, the ESRD Core Indicators
18 established under paragraph (3).

19 “(B) Disseminate recommended clinical prac-
20 tices based on practice guidelines or clinical algo-
21 rithms.

22 “(C) Provide training in quality improvement to
23 the staffs of network administrative organizations to
24 assist the organizations in providing training and as-

1 sistance to providers of services and renal dialysis
2 facilities.

3 “(D) Conduct regional and national peer review
4 of dialysis providers.

5 “(E) Provide technical assistance for quality
6 improvement efforts and identify quality improve-
7 ment activities to reflect evolving needs of patients
8 and facilities.

9 “(F) In consultation with the Work Group (as
10 defined in paragraph (7)), provide guidance to pro-
11 viders of services and renal dialysis facilities on the
12 collection and calculation of the core indicator meas-
13 ures.

14 “(G) Make information and materials under the
15 program available for the use of—

16 “(i) facilities and providers in
17 Medicare+Choice organizations;

18 “(ii) facilities and providers that do not re-
19 ceive payments under this title; and

20 “(iii) private payers of services for end
21 stage renal disease patients.

22 “(3) Not later than 1 year after the date of the enact-
23 ment of this subsection, the Secretary shall publish in the
24 Federal Register the ESRD Core Indicators established
25 as follows:

1 “(A) The Work Group shall define and periodi-
2 cally update ESRD Core Indicators.

3 “(B) The ESRD Core Indicators defined under
4 paragraph (A) may include patient outcome meas-
5 ures based upon the following types of indicators
6 (subject to the establishment of unique measures for
7 kidney transplantation centers) and such other indi-
8 cators as the Work Group considers appropriate:

9 “(i) Adequacy of dialysis.

10 “(ii) Adequacy of nutrition.

11 “(iii) Correction of anemia and average per
12 patient dosage of anti-anemia medications.

13 “(iv) Case-adjusted standardized mortality.

14 “(v) Case-adjusted hospitalization ratios
15 and average length of hospital stay.

16 “(vi) Adequacy of blood pressure control.

17 “(vii) Successful vocational maintenance or
18 rehabilitation.

19 “(viii) Referral for transplantation or self-
20 treatment at home.

21 “(ix) Appropriate administration of clinical
22 lab tests.

23 “(C) To the greatest extent possible, the ESRD
24 Core Indicators shall be developed in conjunction
25 with any relevant quality improvement goals estab-

1 lished by the Secretary or by network administrative
2 organizations which are in effect as of the date of
3 the enactment of this paragraph.

4 “(D) The network administrative organizations,
5 individual renal dialysis facilities, and individual pro-
6 viders of services shall be encouraged to establish
7 additional independent patient-specific and physi-
8 cian-specific or facility-specific core indicators.

9 “(4)(A)(i) Not later than 2 years after the date of
10 the enactment of this subsection, the Secretary shall es-
11 tablish a standard information management system (here-
12 after in this paragraph referred to as “SIMS”) to promote
13 the electronic transfer of data obtained under the CQI
14 Program among providers, facilities, the Secretary, and
15 network administrative organizations. The Secretary shall
16 provide for technical assistance in the use of the SIMS
17 and for the development (or purchase) and distribution of
18 appropriate electronic software for access to the SIMS.

19 “(ii) Under the SIMS—

20 “(I) a facility or provider of services shall con-
21 tribute data to support the CQI Program; and

22 “(II) network administrative organizations shall
23 use data entered into the SIMS to generate clinical
24 profiles on the performance of facilities, based on

1 the ESRD Core Indicators, and shall monitor trends
2 relevant to performance of facilities.

3 “(iii) The SIMS shall be available to all network ad-
4 ministrative organizations and to all facilities or providers
5 of services.

6 “(B) The Secretary shall—

7 “(i) use the SIMS to collect with such fre-
8 quency as the Work Group determines appropriate
9 (but not less frequently than bi-annually) unadjusted
10 data on all patient outcomes required to compute
11 ESRD Core Indicators—

12 “(I) from each provider of services and
13 renal dialysis facility; and

14 “(II) from physicians providing services to
15 individuals determined to have end stage renal
16 disease under this section;

17 “(ii) combine the data collected under clause (i)
18 on individual patients into aggregate data for each
19 provider of services and renal dialysis facility and for
20 each such physician, after taking into account rel-
21 evant factors (including age, gender, race, income,
22 severity of illness, and other morbidities);

23 “(iii) adjust the data combined under clause (ii)
24 to establish comparisons of the core indicator meas-
25 ures of—

1 “(I) each provider and facility with other
2 providers and facilities ; and

3 “(II) each such physician with other such
4 physicians in the network area and the nation;

5 “(iv) create a national core indicator measures
6 database from the data combined and adjusted
7 under this subparagraph;

8 “(v) using unique identifiers to preserve patient
9 confidentiality and confidentiality between providers
10 and facilities, report—

11 “(I) each provider’s and facility’s combined
12 and adjusted data under this subparagraph to
13 the provider or facility and each such physi-
14 cian’s combined and adjusted data under this
15 subparagraph to the physician;

16 “(II) how that provider and facility com-
17 pares in various CQI indicators to other provid-
18 ers or facilities in the same network and in all
19 networks and how that physician compares in
20 various CQI indicators to other physicians; and

21 “(III) such data to the network adminis-
22 trative organization for the network area in
23 which the provider, facility, or physician is lo-
24 cated; and

1 “(vi) provide the data collected under clauses
2 (i), (ii), and (iii) to the United States Renal Dialysis
3 System and other entities engaged in efforts to im-
4 prove the quality of services for renal patients.

5 “(5)(A) For each of three years beginning after De-
6 cember 31, 2001, the Secretary shall identify those dialy-
7 sis facilities and physicians that are 2 standard deviations
8 above the national norm for a preponderance of ESRD
9 Core Indicators on a case severity adjusted basis for 2 con-
10 secutive reporting periods (covering in the aggregate at
11 least 1 year), and shall designate such dialysis facilities
12 and providers as ‘Medicare Dialysis Providers of Achieve-
13 ment’.

14 “(B) Upon request by the network administrative or-
15 ganization for the end stage renal disease network area
16 in which the facility is located, each Medicare Dialysis
17 Provider of Achievement designated under subparagraph
18 (A) shall provide a report on the clinical process and mon-
19 itoring techniques which in the facility’s opinion are most
20 responsible for the facility’s successful outcomes to the
21 network administrative organization for use as a model for
22 other facilities and physicians in the network area.

23 “(C) The Secretary shall maintain and update a list
24 of Medicare Dialysis Providers of Achievement. Not later
25 than March 1 of each of the three years after 2001, the

1 Secretary shall publish such list in the Federal Register.
2 The appropriate network administrative organization shall
3 publicly award such providers of achievement at an annual
4 meeting.

5 “(6)(A) If the Secretary or the network administra-
6 tive organizations for the network area in which a facility
7 or physician is located determines that the dialysis facility
8 or physician is 2 standard deviations below the national
9 norm for a preponderance of ESRD Core Indicators on
10 a case severity adjusted basis for 2 consecutive reporting
11 periods (covering in the aggregate at least 1 year), the
12 Secretary or network administrative organization shall no-
13 tify the facility or physician of such determination.

14 “(B) In the case of a facility notified under subpara-
15 graph (A), the network administrative organization for the
16 network area in which the facility is located, in conjunc-
17 tion with the facility, shall develop strategies to improve
18 the provision of services at the facility and shall provide
19 appropriate training in CQI Program processes to the fa-
20 cility. Such network administrative organization shall re-
21 view the quality of service provided by physicians at such
22 facility for purposes of identifying those physicians that
23 require training in CQI Program processes.

24 “(C) In the case of a physician notified under sub-
25 paragraph (A), the network administrative organization

1 for the network area in which the physician is located, in
2 conjunction with the physician, shall develop strategies to
3 improve the provision of services by the physician, and
4 shall provide appropriate training in CQI Program proc-
5 esses to the physician.

6 “(D) If the Secretary finds that the facility or physi-
7 cian has not made a good faith effort to improve its per-
8 formance under this paragraph, the network administra-
9 tive organization for the network area in which the facility
10 or physician is located—

11 “(i) in the case of a facility, subject to subpara-
12 graph (E), may recommend that the Secretary ter-
13 minate or withhold certification of the facility for
14 purposes of payment for services furnished to indi-
15 viduals with end stage renal disease; and

16 “(ii) in the case of a physician, may recommend
17 to the Secretary—

18 “(I) further investigation of the physician;

19 or

20 “(II) such other actions as the network de-
21 termines appropriate.

22 “(E) In the case of a facility for which the network
23 administrative organization for the network area in which
24 the facility is located proposes to recommend that the Sec-
25 retary terminate or withhold certification of the facility

1 under subparagraph (D), the network administrative orga-
 2 nization shall profile physicians furnishing services at the
 3 facility to determine shared facility/physician responsibil-
 4 ity for the termination.

5 “(7) As used in this subsection:

6 “(A) The term ‘network administrative organi-
 7 zation’ means the organizations described in sub-
 8 section (c)(1)(A).

9 “(B) The term ‘Work Group’ means an ESRD
 10 Core Indicators Work Group appointed by the Sec-
 11 retary and composed of representatives of providers
 12 of renal services, patient advocacy groups, the net-
 13 work administrative organizations, the United States
 14 Renal Data System, patient vocational and rehabili-
 15 tation organizations, quality improvement organiza-
 16 tions, and the Secretary.”.

17 **SEC. 3. RESPONSIBILITIES OF ESRD PROVIDERS, FACILI-**
 18 **TIES, AND NETWORKS.**

19 (a) PARTICIPATION IN CQI PROGRAM AS REQUIRE-
 20 MENT FOR MEDICARE PAYMENT FOR PROVIDERS AND
 21 FACILITIES.—

22 (1) IN GENERAL.—Section 1881(b)(1) of the
 23 Social Security Act (42 U.S.C. 1395rr(b)(1)) is
 24 amended by striking the period at the end of the
 25 second sentence and inserting the following: “, and

1 a requirement that the provider of services or renal
2 dialysis facility meet the requirements of subsection
3 (i) with respect to participation in the CQI Program
4 under subsection (h).”.

5 (2) SPECIFIC REQUIREMENTS DESCRIBED.—
6 Section 1881 of such Act (42 U.S.C. 1395rr), as
7 amended by section 2, is amended by adding at the
8 end the following new subsection:

9 “(i)(1) For purposes of subsection (b)(1), each pro-
10 vider of services or renal dialysis facility shall take such
11 actions as may be required for the provider or facility to
12 participate in the CQI Program under subsection (h), in-
13 cluding the following:

14 “(A) Establishing a CQI team described in
15 paragraph (3) which will have primary responsibility
16 for ensuring that the provider or facility meets the
17 requirements of this paragraph.

18 “(B) Developing and operating a quality im-
19 provement program consistent with the requirements
20 of the CQI Program under subsection (h).

21 “(C) Furnishing information required for the
22 collection and reporting of data under subsection
23 (h)(4).

24 “(D) Posting in a prominent location the data
25 for a provider or facility described in subsection

1 (h)(4)(B) and distributing a copy of the data to each
2 patient.

3 “(E) Taking any other actions which the Sec-
4 retary or the network administrative organization
5 may require in the administration of the CQI Pro-
6 gram.

7 “(2)(A) If the Secretary determines that a facility or
8 provider has failed to report data under the CQI Program
9 or has knowingly and willfully reported false data under
10 the CQI Program, the Secretary may terminate or with-
11 hold certification of the facility or provider for purposes
12 of payment for services furnished to individuals with end
13 stage renal disease.

14 “(B) In the case of a facility or provider whose cer-
15 tification is terminated or withheld by the Secretary under
16 subparagraph (A), if the Secretary determines that infor-
17 mation submitted by such facility or provider is not false,
18 the bar to certification under such subparagraph shall not
19 apply.

20 “(3) The CQI team of a provider of services or renal
21 dialysis facility shall—

22 “(A) consist (at a minimum) of the provider’s
23 or facility’s medical director, director of nursing, so-
24 cial worker, dietitian, chief technician, together with

1 representatives of the provider's or facility's pa-
 2 tients;

3 “(B) periodically hold meetings, which shall be
 4 open to patients and personnel of the provider or fa-
 5 cility, and make minutes of the meetings available to
 6 patients and personnel for a reasonable period of
 7 time;

8 “(C) designate one of its members as the direc-
 9 tor of continuous quality improvement for the pro-
 10 vider or facility and coordinator with the Network
 11 on CQI issues;

12 “(D) consistent with the standards of the CQI
 13 Program under subsection (h), promote clinical prac-
 14 tice guidelines or algorithms for the use of the pro-
 15 vider or facility; and

16 “(E) take any other actions which may be re-
 17 quired to ensure the full participation of the pro-
 18 vider or facility in the CQI Program under sub-
 19 section (h).”.

20 (b) RESPONSIBILITIES OF ESRD NETWORK ADMIN-
 21 ISTRATIVE ORGANIZATIONS.—

22 (1) ASSISTANCE IN OPERATION OF PROGRAM.—

23 Section 1881(c)(2)(B) of such Act (42 U.S.C.
 24 1395rr(c)(2)(B)) is amended by inserting after

25 “(B)” the following: “assisting the Secretary in the

1 administration of the CQI Program under subsection
2 (h) and (consistent with the operation of such Pro-
3 gram)’’.

4 (2) COLLECTION AND DISSEMINATION OF CQI
5 DATA.—Section 1881(c)(2) of such Act (42 U.S.C.
6 1395rr(c)(2)) is amended—

7 (A) by striking “and” at the end of sub-
8 paragraph (G);

9 (B) by redesignating subparagraph (H) as
10 subparagraph (I); and

11 (C) by inserting after subparagraph (G)
12 the following new subparagraph:

13 “(H) collecting and making public data on fa-
14 cilities and providers generated under the CQI Pro-
15 gram under subsection (h) (in accordance with
16 standards established by the Secretary in consulta-
17 tion with representatives of providers, facilities, and
18 patients) and auditing samples of such data to en-
19 sure its accuracy; and”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section shall apply to services furnished 1 year on or
22 after the date of the enactment of this Act.

1 **SEC. 4. STUDY OF FINANCIAL IMPACT OF CQI PROGRAM ON**
2 **ESRD NETWORK ADMINISTRATIVE ORGANI-**
3 **ZATIONS.**

4 Not later than 2 years after the date of the enact-
5 ment of this Act, the Secretary of Health and Human
6 Services shall—

7 (1) analyze the financial impact of the estab-
8 lishment of the ESRD Continuous Quality Improve-
9 ment Program under section 1881(h) of the Social
10 Security Act (as added by section 2) on ESRD net-
11 work administrative organizations under section
12 1881(e) of such Act, and

13 (2) submit to Congress such recommendations
14 as the Secretary considers appropriate to assist the
15 organizations with meeting their responsibilities
16 under such Program.

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